

REMARKS

The Examiner's attention to the present application is noted with appreciation.

FORMAL MATTERS IN PARAGRAPHS NUMBERED 2 THROUGH 8. In paragraphs numbered 2 through 8 of the Office Action, the Examiner has objected to certain informalities in the specification and claims. These are each addressed by amendments to the specification or claims, as appropriate. In brief, in response to paragraph numbered 2 the text of canceled claim 6 is omitted. In response to paragraph numbered 5, each item raised is addressed in amendments to the specification. The sequence that is SEQ ID NO:54 is identified, misspellings are corrected, and SEQ ID NOS are inserted on page 56 and 57. In response to paragraph numbered 6, the word "determined" is deleted from claim 2, and antecedent basis objections are corrected by amendment to the claims. In response to paragraph 7, claim 18 is amended. In response to paragraph 8, claim 39 is amended.

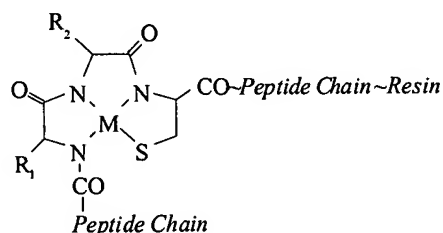
DOUBLE PATENTING REJECTIONS. In response to paragraph numbered 9, it is noted that copending application No. 10/640,755 has a claimed priority date subsequent to that of the instant application. Without conceding that the instant application is obvious over or unpatentable over the copending application, or that the copending application anticipates the instant claims, Applicant submits a terminal disclaimer to facilitate issuance of a patent in this case.

ENTITLEMENT UNDER 35 USC § 119(e) TO BENEFIT OF FILING DATE OF PROVISIONAL APPLICATION 60/148,994. In paragraph numbered 10 of the Office Action, the Examiner asserts that the application is not entitled to the benefit of the filing date of the provisional application 60/148,994 because, under the test of 35 U.S.C. § 112, first paragraph, it does not disclose peptides in general in which the biological-function domain is co-extensive with at least a portion of the metal ion-binding domain, and does not disclose each of the generic formulas recited in claim 18, and in particular does not disclose the

formula corresponding to the elected species R_1 -Bbb-Aaa-Ccc- R_2 . Applicant respectfully traverses this determination.

With respect to the first point, that the provisional does not "disclose peptides in general in which the biological-function domain is co-extensive with at least a portion of the metal ion-binding domain", Applicant points to the following from the provisional application, at page 16, first paragraph:

In one embodiment of this invention, a library is provided in which the metal ion-binding amino acid sequence in the peptides forms a reverse turn structure upon complexation with a metal ion, with the library constructed such that side chains of amino acids within the metal ion-binding sequence are varied, and similarly amino acids not forming a part of the metal ion-binding sequence are also varied. A library of such peptides, therefore, would have at least one of these amino acids that is suitably placed in the sequence, with this amino acid being common to all the molecules in the library, and thus with this amino acid non-randomized. A conceptual, generalized view of a solid phase library of metallopeptides that is constructed using local conformational restriction is:



where M is a metal ion, R_1 and R_2 are either randomly or specifically selected amino acid side chains forming parts of the reverse turn structure which is the potential biological-function domain, and "Peptide Chain" denotes one or more amino acids. A similar library can also be constructed in which the components are soluble, and thus not bound to a resin.

(Emphasis added.) In the quoted description, R₁ and R₂ are defined as “parts of the reverse turn structure.” However, the “reverse turn structure” is simply another way of saying the metal ion binding domain. See, e.g., page 8, second paragraph (“Another object of this invention is to provide combinatorial metallopeptide libraries specific for melanocortin receptors wherein the peptides forming the library contain a reverse turn structure as a consequence of metal ion complexation.”) and page 12, first partial paragraph (“The molecule is designed so that, upon labeling with a metal ion, it forms a mimic of a reverse turn structure about the site of metal ion complexation.”). Thus the provisional application is fully enabling, under the test of 35 U.S.C. § 112, first paragraph, as to claim 2, disclosing a peptide or salt thereof, “wherein at least a portion of said biological-function domain is co-extensive with at least a portion of the metal ion-binding domain.”

Because claim 2 is fully enabled with respect to the provisional application, and because all other claims including claim 18 are dependent claims, it necessarily follows that anticipation rejections under section 102 may not properly be asserted. However, each of the formulas in claim 18 are disclosed in the provisional application, albeit not in the exact language of claim 18. For example, compounds PL-1144, PL-1145 and PL-837 (each on page 29) are each of the general formula corresponding to the elected species R₁-Bbb-Aaa-Ccc-R₂.

REJECTIONS PURSUANT TO 35 USC § 102. In paragraph numbered 12 claims 2, 7 and 8 are rejected as being anticipated by Sharma (U.S. Patent 5,891,418). The rejection is traversed. First, Applicant is entitled to the filing date of the provisional application with respect to claim 2, and hence section 102(b) may not properly be applied. Second, the peptides of Examples 44 and 46 in the Sharma '418 patent each disclose embodiments where the biological function domain (i.e., the sequence His-D-Phe-Arg-Trp) is separate and distinct from the metal ion binding domain (Gly-Gly-Gly-Cys in Example 44, the two carboxymethyl groups in the lysine residues in Example 46 -- see col. 49, lines 55-59). Thus the

compounds of Examples 44 and 46 do not meet the limitation of claim 2, that “at least a portion of said biological-function domain is co-extensive with at least a portion of the metal ion-binding domain.”

In paragraph numbered 13, claims 2, 7, 8, 18, 20, 26-30, 32, 33, 37 and 38 are rejected as being anticipated by Fabris et al. The rejection is traversed. Applicant is entitled to the filing date of the provisional application with respect to claim 2, and hence section 102(b) may not properly be applied. Additionally, claims 7 and 20 are amended such that the metal ion is selected from rhenium and technetium; Fabris et al. teach only zinc-finger peptides.

In paragraph numbered 14, claims 2, 7, 8, 18, 20, 27-30, 32, 33, 37 and 38 are rejected as being anticipated by Shi et al. The rejection is traversed. Applicant is entitled to the filing date of the provisional application with respect to claim 2, and hence section 102(a) may not properly be applied. Additionally, it is noted that the draft poster presentation underlying the Shi et al. abstract was included in the provisional application as Figure 5. Further, the four of the six named authors of the Shi et al. reference are named inventors of the instant application, and accordingly the invention is not “by others” within the meaning of section 102(a). Because Applicant is entitled to the filing date of the provisional, it is asserted that no declaration regarding invention is required. However, if required Applicant will submit a declaration in accord with 37 CFR 1.131 or 1.132.

In paragraph numbered 15, claims 2, 7, 8, 18, 20, 26-29, and 33 are rejected as being anticipated by Giblin et al. The rejection is traversed. Applicant is entitled to the filing date of the provisional application with respect to claim 2, and hence section 102(b) may not properly be applied. Additionally, the Giblin et al. reference specifically teaches away from a biological-function domain which is co-extensive with at least a portion of a metal ion-binding domain, and teaches away from the compounds being more specific when in the complexed state in comparison to the uncomplexed state. See, e.g., page 12815, third full paragraph, stating “[t]he metal-binding site must be engineered so that metal coordination does not disrupt the biologically active conformation of the molecule.” Further, in each

example of Giblin et al. two cysteine residues are employed for rhenium binding, while claim 18 contains only a single cysteine (or other residue Ccc providing both a sulfur and nitrogen for binding).

In paragraph numbered 16, claims 2, 8, 18, 26-30, 32, 37 and 38 are rejected as being anticipated by Deghenghi (U.S. Patent 5,668,254). The rejection is traversed. Claim 2 is amended to further provide a metal ion complexed to the metal ion-binding domain. This is neither taught nor suggested by Deghenghi.

In paragraph numbered 15, claims 2, 8, 18, 26-30, 32, 37 and 38 is rejected as being anticipated by Keri et al. (U.S. Patent Application Publication 2001/0009899). This is a rejection under section 102(e). The rejection is traversed. Claim 2 is amended to further provide a metal ion complexed to the metal ion-binding domain. This is neither taught nor suggested by Keri.

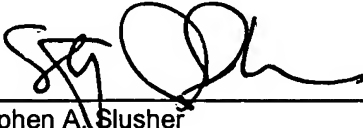
EXTENSION. A petition for a two month extension, through November 29, 2004, and the required fee, is submitted herewith. Authorization is given to charge payment of any additional fees required, or credit any overpayment, to Deposit Acct. 13-4213. A duplicate of this paper is enclosed for accounting purposes.

In view of the above amendments and remarks, it is respectfully submitted that all grounds of rejection and objection have been avoided and/or traversed. It is believed that the case is now in condition for allowance and same is respectfully requested.

If any issues remain, or if the Examiner believes that prosecution of this application might be expedited by discussion of the issues, the Examiner is cordially invited to telephone the undersigned attorney for Applicant at the telephone number listed below.

Respectfully submitted,

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